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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/973,363	02/04/1998	RICHARD GRIFFITHS	263PPNTIR117	6817

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/973,363	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *04 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *34,36,40,42,44,46,48,49,56-59 and 61-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *34,36,40,42,44,46,48,49,56-59 and 61-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

An amendment was received and entered on 11/4/03.

New claims 62-67 were added as requested.

Claims 34, 36, 40, 42, 44, 46, 48, 49, 56-59, and 61-67 are pending and under consideration in this Office Action.

Objections Withdrawn

Applicant's amendments were sufficient to place the Application in compliance with the Sequence Rules, and to overcome the objections to the specification at page 29, and to claims 48 and 49.

Rejections Withdrawn

Applicant's amendments to claims 36, 40, and 48 were sufficient to overcome the rejection of these claims under 35 USC 112, first paragraph for lack of adequate written description.

Applicant's amendments to claims 36, 40, 44, 46, 48, 49, and 56 were sufficient to overcome the rejection of these claims under 35 USC 112, first paragraph for lack of adequate enablement.

Applicants amendments to claims 56 was sufficient to overcome the rejection under 35 USC 102.

After further consideration, the rejection of claims 57-59 for lack of written description and enablement is withdrawn. While the specification does not disclose

primers that give rise to CHD-W and CHD-1A PCR products that can be distinguished from each other on the basis of size without further treatment, the specification shows that the products can be discriminated by restriction digestion, and it is readily apparent to one of skill in the art that a representative sample of PCR products could be cloned and sequenced, and that the results of this sequencing should indicate whether a +CHD-W allele had been amplified, thereby allowing sex determination.

Claim Objections

Claim 36 is objected to because it lacks an article before the noun "restriction endonuclease."

Claims 36 and 44 are objected to because they lack an article before the noun "hybridising restriction fragment."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 34, 36, 40, 44, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 36, 40, 44, 46 have been amended to recite "A chromosomes". The specification as filed does not support this term. As discussed below under 112, second paragraph rejections, the meaning of the term is unclear. In the event that Applicant intended to imply "autosomal" by 'A', this would also represent new matter as the specification clearly teaches that it is not known on whether the non-W CHD-genes are autosomal or Z-linked. See e.g. page 36, lines 24-26.

Claim 34 was included in this rejection only because it is the parent to each of the claims that explicitly recite the new matter. As such, it must also comprise the new matter.

Written Description

Claims 42, 44, 46, 49, 56, 62, and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 42, 44, 46, 49, 62, and 64 are drawn to the genus of polynucleotides that hybridize under high stringency conditions to SEQ ID NOS: 1, 3, 5, 10, 12, 13, or 15. The specification discloses that none of SEQ ID NOS: 1, 3, 5, 10, 12, 13, or 15 corresponds to a complete open reading frame, as each of these sequences is either a

partial cDNA or partial genomic clone. However, the claimed genus clearly embraces complete cDNAs and genomic clones because it embraces any isolated polynucleotide that hybridizes under stringent conditions to SEQ ID NOS: 1, 3, 5, 10, 12, 13, or 15.

The specification fails to describe a single species of complete cDNA or genomic clone, and fails to establish any correlation between structure and function that would allow one of skill in the art to envision the sequences of complete cDNAs and genomic clones. For this reason one of skill in the art could not conclude that Applicant was in possession of the claimed invention at the time the invention was filed.

Claim 56 is drawn to the genus of isolated polynucleotides consisting of a sequence that encodes a polypeptide having the amino acid sequence of SEQ ID NOS: 7-9, 11, or 14. This claim also reads on full length cDNAs and genomic clones encoding any bird CHD gene. SEQ ID NOS: 7-9, 11, and 14 correspond to avian CHD polypeptides encoded by partial cDNAs. The specification discloses various genomic and cDNA fragments of CHD genes from the mouse and from two birds, but fails to disclose any full-length cDNA of any avian CHD gene, any full-length genomic clone of any avian CHD gene, any common sequence which is shared by all the members of the claimed genus, nor any sequence characteristic which identifies any sequence as having been derived from a bird rather than from some other animal. Because the disclosed sequences do not include any full-length genomic or CDNA clones, and include no sequence identified as common to all the members of the claimed genus, the disclosed sequences do not constitute a substantial portion of the claimed genus. Weighing the available evidence, i.e. the lack of disclosure of any full-length cDNA or

genomic clone, the breadth of the claims which clearly encompasses such sequences, and the failure to identify any sequence common to all of the members of the genus, one of skill in the art could not conclude that Applicant was in possession of the claimed genus at the time of filing.

Response to Arguments

Applicant's arguments filed 11/4/03 have been fully considered but they are not persuasive.

At page 12 of the response Applicant states that the rejection of claims 44 and 46 is believed to be overcome by the amendment. Applicant gives no reason why the amendment is considered to limit the claims to adequately described material. Because the claims still embrace nucleic acids encoding full length cDNAs and genomic clones, which applicant has not demonstrated possession of, the rejection is maintained.

With regard to claim 56, Applicant asserts that knowledge of the amino acid sequence of a protein suffices as a description of all of the nucleic acid sequences that could encode that protein. This is true, but is irrelevant to the grounds of the rejection which state that the claim reads on full length genomic clones and full length cDNAs of which Applicant has not demonstrated possession, so the rejection is maintained.

With respect to claims 57-59, Applicant argues that 3 primers have been reduced to practice, and that primers of greater and shorter lengths can be synthesized based on the disclosed template sequences in the specification. This is irrelevant. The claims embody primer sets that give rise to different sized PCR products depending on the

template to which they are applied, i.e. a set of primers that gives one size PCR product when applied to a CHD-W template and a different size PCR product when applied to a CHD-1A template, thereby allowing sex discrimination without further treatment of the PCR products. The results of record indicate that the disclosed primers give rise to PCR products that are exactly the same size regardless of the template to which they are applied, i.e. CHD-1A or CHD-W. In other words, Applicant is not in possession of PCR primers that give rise to PCR products that allow one to distinguish CHD1-A PCR products from CHD-W PCR products on the basis of size. In order to do this one must digest the PCR products with a restriction enzyme that gives different sized products. The rejection is maintained.

Enablement

Claims 57-59, 65, and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining the sex of a non-ratite bird, or of an embryo, fetus, cell, or tissue of a non-ratite bird comprising subjecting to restriction digestion or DNA sequencing DNA amplified nucleic acid samples of said non-ratite bird, embryo, fetus, cell, or tissue, wherein the restriction digest gives rise to fragments of CHD-W and CHD1-A genes that can be discriminated on the basis of size, does not reasonably provide enablement for methods of determining the sex of a non-ratite bird, or of an embryo, fetus, cell, or tissue of a non-ratite bird based solely on discriminating the size of undigested PCR products. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention commensurate in scope with these claims.

As discussed above under written description, claims 57-59 65, and 66 are drawn methods of using primer oligonucleotides to amplify a product from a CHD-W gene that is distinguishable by its size from any product amplified with the same primers from a CHD-IA gene. The claims embrace an embodiment wherein PCR products are subjected to a diagnostic restriction digest. This embodiment is enabled. The specification also embraces methods that do not allow for diagnostic restriction digestion, but which require the simultaneous generation of different sized PCR products from CHD-W and CHD-IA templates using the same primers. The specification fails to teach any primer set that achieves this result, and the evidence of record indicates that it is not possible. The specification discloses a single set of nested PCR primers and shows that PCR products amplified from three species of birds all gave rise to only a single length product, therefore the PCR products generated from CHD-IA and CHD-W templates were of identical length. In fact, the specification teaches that it is a criterion for PCR-based sex determination that the PCR products must be separable by restriction digestion. See page 28, lines 26 and 27. Because the specification does not teach any example of PCR primer pairs that can be used to amplify different sized CHD-W and CHD-IA products, and explicitly states that restriction digestion is necessary to resolve the products, one of skill in the art would have to perform undue experimentation in order to practice the claimed invention commensurate in scope with its breadth, i.e. to discriminate without restriction digestion CHD-W and CHD-1A PCR

products generated from any set of PCR primers that could be designed based on the instant disclosure.

Response to Arguments

Applicant's arguments filed 11/4/03 have been fully considered but they are not persuasive.

Applicant considers the enablement rejection at pages 13-14 of the response. The essence of the argument appears to be that the specification need not enable every conceivable embodiment, based on the courts finding that what is well known is best omitted.

The claimed invention can be conceived in at least three broad embodiments. These include determining sex of birds by;

1) direct analysis by gel electrophoresis of PCR products that can be differentiated by size without need for restriction digestion.

2) analysis by gel electrophoresis of PCR products that have first been digested with a restriction endonuclease that gives rise to fragment sizes that are diagnostic of CHD-W and CHD-1A genes.

3) analysis by DNA sequencing of PCR products

Applicant's arguments are unpersuasive because they present no evidence or logic to indicate that the claims do not embrace methods of determining non-ratite bird sex by directly measuring the size of PCR products, without restriction digestion or sequencing of those products. Applicant has presented no evidence or argument that

this scope of the claimed invention is somehow insignificant and should be overlooked in considering enablement of the claims. It seems clear that one of skill in the art would consider it simpler and faster to be able to determine the sex of birds by directly assaying the size of PCR products without having to first perform a diagnostic restriction digest or assay PCR products by sequencing. However, as discussed above in the rejection, the specification as filed does not teach how to do this. Therefore this scope of the claimed invention could be viewed as an improvement on what the specification fairly teaches how to do, and it would be improper to grant Applicant protection for this scope of the claimed invention. For this reason the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 36, 40, 44, and 46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 36, 40, 44, and 46 are indefinite because it is unclear what is intended by "A chromosomes". This is not a term of art and is not defined in the specification, thus one of skill in the art cannot know the metes and bonds of the claims. Claim 34 was included in this rejection only because it is the parent to each of the claims that explicitly recite the indefinite term. As such, it must also comprise the indefinite term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 67 is rejected under 35 U.S.C. 102(e) as being anticipated by Brennan (US Patent 5,474,796, issued 12/12/95).

Brennan teaches an array of isolated oligonucleotides comprising every conceivable 10mer oligonucleotide sequence. See column 9, lines 48-55. Thus Brennan teaches every 10 nucleotide fragment of SEQ ID NOS: 1, 3, 4, 5, 10, 12, 13, and 15.

Conclusion

No claim is allowed.

Claims 48, 61, and 63 are objected to as depending from a rejected claim, but would be allowable if rewritten in independent form with all of the limitations of the parent claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at 703-306-3217 before 2/22/04, and at 571-272-0811 after 2/22/04. The official central fax number is 703-872-9306 until further notice. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.